

SCHEMA - PROTOCOL P

<u>TITLE:</u>	A randomized clinical trial to evaluate the effectiveness of antiretroviral therapy (ART) plus HIV primary care versus HIV primary care alone to prevent sexual transmission of HIV in serodiscordant couples.
<u>DESIGN:</u>	Phase III, two arm, randomized, controlled, multi-center trial.
<u>POPULATION:</u>	HIV-serodiscordant couples in which the HIV-infected partner is ART naïve.
<u>DURATION:</u>	All couples will be followed until the last couple enrolled has completed 60 months of follow-up.
<u>PRIMARY OBJECTIVE(S):</u>	To compare the rates of HIV infection among partners of the HIV-infected participants in the two trial arms.
<u>SECONDARY OBJECTIVES:</u>	<p>To determine the long-term safety of two ART regimens for the treatment of HIV-1 infection.</p> <p>Characterize and compare patterns of antiretroviral (ARV) drug resistance of the two ARV treatment strategies.</p> <p>Assess factors associated with adherence and compare adherence of the two ARV treatment regimens.</p> <p>Evaluate the effectiveness of couples HIV counseling and characterize the patterns of sexual behavior in couples in both arms of the trial.</p>

SCHEDULES OF EVALUATIONS FOR THE FIRST 12 MONTHS - PROTOCOL P (INDEX CASE)

PROCEDURES	SCREENING ENROLLMENT			STUDY MONTHS												
	S	E	Wk 1	1	2	3	4	5	6	7	8	9	10	12	Partner seroconverts	d/c
Informed consent	X	X														
Determine HIV status	X															X
Sexual history		X		X			X				X			X	X	X
Adherence assessment																X
Couples HIV counseling	X	X	X	X			X				X			X	X	X
Adherence counseling		X	X	X			X				X			X	X	X
Medical history and physical exam	X	X		X	X	X	X	X	X	X	X	X	X	X		X
Urinalysis	X	X		X			X				X			X	X	X
Genital exam		X												X		X
Pelvic exam		X												X	X	X
Wet mount (Bacterial vaginosis)		X												X	X	X
Wet mount (Candidiasis)		X												X	X	X
Wet mount (Trichomoniasis)		X												X	X	X
Pregnancy test	X	X		X			X				X			X		X
Hematology	X	X	X	X			X				X			X		X
Chemistry panel	X	X	X	X			X				X			X		X
RPR		X												X		X
CD4+ and CD8+ cell counts	X	X												X	X	X
HIV Plasma RNA		X					X				X			X	X	X
Specimen storage: cervical wick or seminal fluid		X												X		X
Specimen storage: vaginal swabs		X												X		X

SCHEDULES OF EVALUATIONS FOR THE FIRST 12 MONTHS - PROTOCOL P (PARTNER)

[illegible]